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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/067,337	04/27/1998	HUBERT KOSTER	24743-2301	9981

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EXAMINER

YOUNG, JOSEPHINE

ART UNIT	PAPER NUMBER
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1623

34

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/067,337

Applicant(s)

KOSTER ET AL.

Examiner

Josephine Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 October 2002 and 24 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5-7, 11-16, 29, 33-37, 39, 45 and 49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-7, 11-16, 29, 33-37, 39, 45 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 10, 13.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 34.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Species A, directed to liquid phase carriers (LPCs) of formula (Ia) and methods for using the same, in Paper No. 15, mailed January 18, 2000, is acknowledged. Further, Applicant's election without traverse of Species A, directed to liquid phase carriers that do not contain 2'-deoxythymidine-3'-O-yl and methods for using the same, in Paper No. 24, mailed August 6, 2001, is acknowledged.

The restriction requirement made in Paper No. 27, mailed January 16, 2002, is hereby withdrawn. Therefore, claims previously withdrawn from consideration as a result of a restriction requirement are now rejoined and fully examined for patentability under 37 CFR 1.104.

### ***Rejections Set Forth in the Office Action dated July 16, 2002***

Claims 5-9, 27-40 and 45-49 were provisionally rejected under the judicially created doctrine of double patenting over claims 6, 7, 9-11, 14-17, 20-22, 25, 26, 29, 31, 32, 39, 40, 45 and 47-49 of copending Application No. 09/484,484.

Claims 5-9, 27-40 and 45-49 were rejected under 35 U.S.C. 103(a) as being unpatentable over Patent No. US 5,198,540 to KOSTER et al.

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***Response to the Amendment filed October 16, 2002***

The Amendment, filed October 16, 2002, has been received, entered into the record and carefully considered.

Claims 8-10, 17-28, 30-32, 38, 40-44 and 46-48 were canceled. Claims 5, 7, 11-14, 33, 37, 39 and 45 were amended.

An action on the merits of claims 5-7, 11-16, 29, 33-37, 39, 45 and 49 is contained herein below.

In regards to the Provisional Rejection of claims 5-9, 27-40 and 45-49 under the judicially created doctrine of double patenting, Applicant's Amendments filed October 16, 2002 have been fully considered, but they are not persuasive. The Rejection of the claims is maintained for the reasons of record as set forth in the Office Action dated July 16, 2002.

In regards to the Rejection of claims 5-9, 27-40 and 45-49 under 35 U.S.C. 103(a) as being unpatentable over KOSTER, Applicant's Amendments filed October 16, 2002 have been fully considered and have overcome the Rejection set forth in the Office Action dated July 16, 2002 (claims amended).

***Response to Arguments filed October 16, 2002***

Applicant's Arguments filed October 16, 2002 have been fully considered but they are not persuasive.

In response to Applicant's Request to defer the issue of obvious-type double patenting, since such issue cannot be properly assessed until there is allowable subject matter, it is noted

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that since the rejection was a provisional rejection, such issue can be deferred until the indication of allowable subject matter.

***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-7, 11-16, 29, 33-37, 39, 45 and 49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A written description analysis involves three principle factors:

- (1) field of the invention and predictability of the art,
- (2) breath of the claims, and
- (3) possession of the claimed invention at the time of filing for each claimed species/genus.

The claims are directed to liquid phase carriers (LPC), in particular of formula (Ia) that do not contain 2'-deoxythymidine-3'-O-yl and methods for using the same in solution phase biopolymer synthesis. The breath of the claim is such that silicon is substituted with Z-X<sup>1</sup>, wherein Z is 1-12 units of 1,4-phenylene or methylene groups, t is 1-12 and X<sup>1</sup> is any reactive group. The specification presents particular compounds of formula (Ia) that do contain 2'-

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deoxythymidine-3'-O-yl, namely, tetrakis{6,9-diaza-13-[5'-O-(4,4'-dimethoxytriphenylmethyl)-2'-deoxythymidine-3'-O-yl]-2-oxa-5,10,13-trioxotridecyl}-methane ((DMT-dT)<sub>4</sub>-PE-LPC) and tetrakis[13-(2'-deoxythymidine-3'-O-yl)-6,9-diaza-2-oxa-5,10,13-trioxotridecyl]-methane (dT<sub>4</sub>-PE-LPC), as well as their chemical preparation (page 37-41 of the specification). The specification states that other LPCs of formulae (Ia) may be prepared by minor modifications of this method. However, a statement of a potential synthetic method based on the synthesis of compounds not within the general definition of the formula (Ia) as instantly claimed does not constitute a sufficient written description for how to make LPCs of formula (Ia) wherein A is silicon; moreover, the support in the specification is not adequate for the claim to the method of solution phase biopolymer synthesis using said LPCs.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by functional characteristics sufficient to show the Applicant was in possession of the claimed genus. There are a variety of compounds of formula (Ia) wherein A is silicon that do not contain 2'-deoxythymidine-3'-O-yl, for which there is not seen support for how to make and use in the instant disclosure. There is no predictability established in the art with respect to synthesizing a substituted silicon compound based on the synthesis of a substituted methane compound. Further, there are a variety of compounds of formula (Ia) wherein A is silicon, each substituted with Z-X<sup>1</sup>, wherein Z is 1-12 units of 1,4-phenylene or methylene groups and X<sup>1</sup> is any reactive group, i.e. an alkyl, phenyl, alkylphenyl or phenylalkyl terminally substituted with a heteroatom or carbonyl, for which there is not seen support for how to make and use in the instant disclosure. There is no predictability established in the art with respect to synthesizing a silicon atom substituted with an alkyl,

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phenyl, alkylphenyl or phenylalkyl based on the synthesis of methane tetra-substituted with 8-amino-6-aza-2-oxa-5-oxooctyl. To provide adequate support for the breadth of the claims, Applicant would have to establish that the methodology for carbon-carbon bond formation is the same for attaching an alkyl or phenyl group to a silicon based compound as for attaching an amide to methane. The data presented shows the synthesis of methane substituted with an amide or diamide, which it not seen to be adequately correlative for the elected species of a silicon based compound substituted with an alkyl or phenyl group as is broadly claimed. An adequate representation of species requires that the species that are expressly described be representative of the entire genus and what constitutes a "representative number" is an inverse function of the predictability of the art. As such, a skilled artisan would not recognize that a compound capable of being synthesized via standard carbonyl chemistry would be representative of compounds incapable of being synthesized in a similar manner. Further, a skilled artisan would not recognize that a diamide compound linked to a nucleoside would be representative in function to the silicon-based alkyl, phenyl, alkylphenyl or phenylalkyl compound as broadly claimed. As such, there is not seen any data that supports Applicant's claim that at the time of filing, the compounds of the invention were made and used by minor modification to the protocol developed for the diamide compounds.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 5-7, 11-13, 29, 33-37, 39, 45 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "any reactive group" in independent claim 5, 33 and 45 renders the claims in which it appears indefinite. In the absence of particular moieties that would be construed as a reactive group or distinct language to describe the structural features or the chemical names of the reactive group of this invention, the identity of said reactive group would be difficult to describe and the metes and bounds of said reactive group that Applicant regards as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

The term "pseudohalide" in dependent claims 6 and 39 renders the claims in which it appears indefinite. In the absence of particular moieties that would be construed as pseudohalides or distinct language to describe the structural features or the chemical names of pseudohalides of this invention, the identity of said pseudohalide would be difficult to describe and the metes and bounds of said pseudohalide that Applicant regards as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

### ***Conclusion***

Claims 5-7, 11-16, 29, 33-37, 39, 45 and 49 are pending. Claims 5-7, 11-16, 29, 33-37, 39, 45 and 49 are rejected. No claims are allowed.



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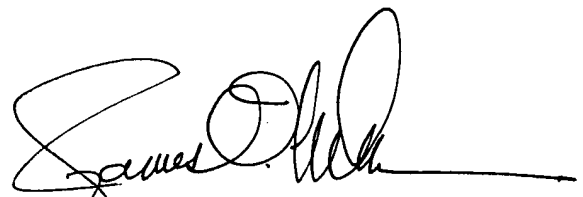
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Josephine Young whose telephone number is (703) 605-1201.

The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JY  
April 21, 2003



**JAMES O. WILSON**  
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